K080318

MAR - 7 2008

Section 5 – 510(k) Summary or 510(k) Statement

I. General Information

Submitter: Alma Lasers, Ltd.
Halamish Street (PO Box 3021), Industrial Park,
Caesarea, 38900
ISRAEL

Contact Person: Tatiana Epstein
Regulatory Affairs Manager,
Alma Lasers, Ltd.

Summary Preparation Date: January 30th, 2008

II. Names

Device Names: Alma Lasers NIR Module

Primary Classification Names: Lamp, Infrared, Therapeutic Heating

III. Predicate Devices

- K050370 – Palomar LuxIR Handpiece – Palomar Medical Technologies, Inc.
- K042165 - Cutera Titan Tabletop Product – Cutera, Inc.
- K033768 – Altus Medical Optional Infrared Handpiece – Cutera, Inc. (cleared under the former company name of Altus Medical, Inc.).

IV. Product Description

The Alma Lasers NIR Module is an additional module to the existing Alma Lasers, Ltd. (former MSq.) Soprano Diode Laser System cleared under K052874.

The Alma Lasers NIR Module is comprised of the following components:

- An 'umbilical' cable and connector, that is permanently attached to the NIR module body and semi-permanently attached to the laser system that houses:
- Electrical cables (to support the thermoelectric coolers (TEC) associated with the chilled sapphire window, to provide power to the pulsed light source (quartz tube), and to connect to a memory device that identifies the module)
- A supply and return water line (to remove the heat generated by the infrared lamp and thermoelectric cooler)
- Module body (shells) housing the module internals and connecting to the umbilical.

The light source emits a pulse when it is activated by pressing the footswitch. The light passes through an aperture with a filter, into a lightguide that is located on the module tip. The operator holds the handpiece by its handle in order to position the lightguide against the patient's skin.

The module tip is TEC-cooled to provide contact skin cooling. The module contact cooling mechanism can be turned on or off by touching the appropriate soft-key in the bottom-left corner of the LCD control panel. The temperature at the skin surface does not exceed 40°C.
The NIR module is operated only by pressing the footswitch.

The proximal end of the umbilical is semi-permanently attached to the laser system console and the distal end is permanently attached to the body of the NIR delivery module. The Alma Lasers NIR Module is removable by either the user or an authorized filed service engineer for replacement at the proximal end.

V. Indications for Use

The Alma Lasers NIR Module is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature for the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

VI. Rationale for Substantial Equivalence

The Alma Lasers Alma Lasers NIR Module shares the same indications for use, the operation, technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Alma Lasers NIR Module is substantially equivalent to the predicate devices.

VIII. Conclusion

The Alma Lasers Alma Lasers NIR Module was found to be substantially equivalent to the predicate devices.

The Alma Lasers Alma Lasers NIR Module shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alma Lasers, Ltd.
% Ms. Tatiana Epstein
RA Manager
Halamish Street, P.O. Box 3021
Industrial Park
Caesarea 38900
Israel

MAR - 7 2008

Re: K080318
Trade/Device Name: Alma Lasers NIR Module
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: February 28, 2008
Received: March 1, 2008

Dear Ms. Epstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): **K08**

Device Name: **Alma Lasers NIR Module**

Indications for Use:

The Alma Lasers NIR Module is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature for the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080318